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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638
20995	7590	11/08/2007		
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 11/08/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/614,650

Applicant(s)

ZHU ET AL.

Examiner

Melanie J. Hand

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15, 17-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-9, 11-15, 17-20 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 21, 22, 24, 34, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

Applicant's arguments, see Remarks, filed October 1, 2007, with respect to the rejection of claims 10, 21, 22, 24, 34 and 35 under 35 U.S.C. 112 have been fully considered and are persuasive. The rejection of claim 35 under 35 U.S.C. 112 has been withdrawn.

Applicant's arguments, see Remarks, filed October 1, 2007, with respect to the rejection(s) of claim(s) 10, 21, 22, 24, 34 and 35 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the previously applied Hammerslag reference. Briefly, the embodiment of the instant applicator having sheath 250 and second lumen 270 shown in Fig. 7 is a modification of an embodiment in which introducer sheath 250, which is movable along lumen 80, is not present (i.e. the embodiments of Figs. 4-6) but the device still performs the function of patch applicator. Hammerslag also teaches an embodiment of a method of the instant invention in which sheath 250 with second lumen 270 is either mounted on said first lumen prior to catheterization, or is left in place after catheterization and prior to patching. Thus, Hammerslag is teaching an alternative embodiment in which the first and/or said second lumen (either sheath 250 or cannula 270) are integral and thus always move as a single elongate unit (Col. 11, lines 50-55, 60-66).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10, 21, 22, 24, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerslag et al ('194).

With respect to **Claim 10**: Hammerslag teaches a tissue closure device comprising an elongate body with a first portion 80 and a second portion 270 having a lumen, each portions having a distal end; the second portion 270 cannot be moved distally (i.e. said portion is a rigid fixture) relatively to the first portion distal end beyond the minimum distance and is arranged concentrically around the first portion 80.

Hammerslag does not explicitly teach that the first and second portions are rigidly connected to one another so as to always move as a single elongate unit. However, the embodiment of the instant applicator having sheath 250 and second lumen 270 shown in Fig. 7 is a modification of an embodiment in which introducer sheath 250 is not present (i.e. the embodiments of Figs. 4-6). Hammerslag also teaches an embodiment of a method of the instant invention in which sheath 250 with second lumen 270 is either mounted on said first lumen prior to catheterization, or is left in place after catheterization and prior to patching. Thus, Hammerslag is teaching an alternative embodiment in which the first and/or said second lumen (either sheath 250 or cannula 270) are integral and thus always move as a single elongate unit (Col. 11, lines 50-55, 60-66). Therefore it would be obvious to one of ordinary skill in the art to

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modify the device of Hammerslag such that said first lumen and said second lumen are rigidly connected to one another so as to always move as a single elongate unit.

With respect to **Claim 21**: Hammerslag teaches a tissue closure device comprising an elongate body comprising a first lumen 80 having a first distal opening and a second lumen 270 having a second distal opening, the lumens being arranged so that a longitudinal space is defined between the first and second distal openings as indicated in Fig. 11. Wound cover member 88 is releasably connected to the elongate body at said first distal opening, as is also seen in Fig. 11. The first distal opening is permanently maintained at a position distal of the second distal opening prior to advancement and release of patch 88 and the first lumen 80 and second lumen 270 do not communicate with one another. (Col. 13, lines 62-67, Col. 14, lines 1-5) In light of the rejection of claim 21 under 35 U.S.C. 112, Hammerslag is applied herein as prior art anticipating claim 21.

With respect to **Claim 22**: The second lumen 270 is configured as an applicator to communicate a flowing fluid therethrough, i.e. the fluid that forms patch 88. (Col. 2, lines 21-24, Col. 4, lines 21-23, Col. 13, lines 62-64)

With respect to **Claims 24,34**: Hammerslag teaches that the applicator of the instant invention additionally comprises a release rod 26 sized and configured to slide through first lumen 80 and into contact with adhesive 16 (or alternatively, wound cover member 88). (Col. 4, lines 20-22)

With respect to **Claim 35**: The wound cover member, patch 88, has a diameter that is greater than a maximum diameter of the second lumen distal opening.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on M-Th 8-5, alt Fri. 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

October 29, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

